

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: <i>Wave 8 Cases Listed in Exhibit A</i> ¹	WAVE 8 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE
OPINIONS AND TESTIMONY OF DOROTHY KAMMERER-DOAK, M.D.**

Defendants submit this response in opposition to the Plaintiffs' motion to exclude certain opinions and testimony of Dorothy Kammerer-Doak, M.D. (Doc. 6882) and the memorandum in support of that motion (Doc. 6885). Plaintiffs' argue that several of Dr. Kammerer-Doak's opinions are beyond the scope of her expertise or based on unreliable methodologies. However, her testimony as to commonly known risk factors and the association between pain and midurethral slings is based upon the scientific literature as well as her extensive clinical experience. As for her "testimony" as to her own patient satisfaction rates and complication statistics, no such testimony exists. Therefore, as more fully explained below, Plaintiffs' motion to exclude should be denied.

BACKGROUND

Dorothy Kammerer-Doak, M.D., is a board certified obstetrician and gynecologist with a subspecialty in female pelvic medicine and reproductive surgery ("FPMRS"). Doc. 6882-2, Pls.' Ex. B, General Expert Report of Dorothy Kammerer-Doak, M.D., ("Report") at 1. Dr. Kammerer-Doak completed her four-year residency in obstetrics and gynecology at the

¹ Plaintiffs' motion and this response are related to the cases listed in Plaintiffs' Exhibit A, Doc. 6882-1.

University of California, Irvine, followed by a fellowship in advanced gynecological surgery at the Mayo Clinic in Scottsdale, Arizona. Doc. 6882-2 at 67. After her fellowship, in 1992, she joined the faculty at the University of New Mexico Hospital's ("UNMH") Department of Obstetrics and Gynecology, where she formed a training program for the then-nascent subspecialty of urogynecology and pelvic floor medicine. Report at 2. Throughout her career, she has published more than 40 peer-reviewed articles, given numerous invited lectures and refereed presentations, and participated in many trials and research projects. Doc. 6882-2 at 70-85. Though she remains active with research and training of residents at UNMH, Dr. Kammerer-Doak has been in private practice, focusing on gynecology and FPMRS, since 2009. Report at 3.

When Dr. Kammerer-Doak joined the faculty at UNMH, the only surgical procedure being done to treat uncomplicated stress urinary incontinence was the anterior colporrhaphy with Kelly plication. Report at 2. In 1999, Dr. Kammerer-Doak instigated a randomized, controlled trial comparing this procedure with the Burch urethropexy and demonstrated that the Burch method was superior. *Id.* For recurrent or severe stress urinary incontinence, however, the pubovaginal suburethral sling remained the preferred surgical treatment. *Id.* Through the years, physicians continued the search for the ideal material for urethral slings, using such materials as fascia harvested from the patient, sutures, and ultimately transvaginal tape ("TVT"). *Id.* A study in 2004 comparing the Burch method with the use of TVT slings demonstrated equivalent efficacy, but the TVT slings had lower morbidity rates. *Id.* at 2-3. At that point, Dr. Kammerer-Doak adopted the TVT slings and offered them to her patients; since then, she has performed at least 2000 TVT sling procedures, both in isolation and in combination with pelvic organ prolapse repairs. *Id.* at 3.

ARGUMENT

Defendants incorporate by reference the standard of review for motions to exclude experts as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. Dr. Kammerer-Doak's testimony as to what risk factors were known to physicians in her field is probative as to causation and should be allowed.

Plaintiffs argue that Dr. Kammerer-Doak's testimony related to what risk factors were known to physicians in her field should be excluded, because she is not an FDA labeling expert and did not adequately address contrary scientific evidence. Doc. 6885 at 3-6. However, her testimony is reliably founded upon the scientific literature and her own clinical experience, and this testimony is within her expertise.

Dr. Kammerer-Doak explained that certain risk factors, such as dyspareunia and recurrent incontinence, are and have been well known to physicians in her field. Report at 17. In so doing, she did not rely only upon her own personal training and experience or anecdotal evidence; she cited a number of educational materials, professional guides, and medical school curricula demonstrating the generally known risk factors of TVTs. *Id.* “[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings.” *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015); *see also Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) (“[E]xpert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts.”); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (concluding testimony regarding common

knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

Dr. Kammerer-Doak is not an FDA labeling expert per se² and will not be offering opinions regarding regulatory compliance, and whether Ethicon complied with all FDA requirements and regulations is not at issue in this case. However, to establish causation, Plaintiffs must demonstrate, among other things, that “the manufacturer failed to warn the physician of a risk not otherwise known to the physician.” *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673-74 (Ala. 2014); *see also, e.g., Gilliland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 960, 969-70 (S.D. Iowa 2014) (recognizing known-risk argument but denying summary judgment because of fact issue as to whether prescribing oncologists were aware of a risk.”); *Begley v. Bristol-Myers Squibb Co.*, No. Civ. A. 06-6051, 2013 WL 144177, at *4 (D.N.J. Jan. 11, 2013) (“As a corollary to the learned intermediary doctrine, drug manufacturers are not obligated to warn prescribing physicians of risks already known to the medical community . . . because ‘there is no duty to warn of a risk that is already known by those to be warned[.]’”) (internal citations omitted) (applying Illinois law); *Gray v. Badger Min. Corp.*, 676 N.W.2d 268, 275-76 (Minn. 2004) (“By applying traditional common law causation principles, we concluded that the failure of a drug manufacturer to warn a physician of the dangers of a drug was not the proximate cause of the injury to the patient where the physician acknowledged that he was fully aware of its potentially dangerous side effects.”).

² Despite Plaintiffs’ argument suggesting otherwise, Doc. 6885 at 3, that the meaning behind the IFU acronym slipped her mind after nearly 3 hours of deposition testimony is no reflection on her understanding of IFUs generally. Doc. 6882-3, Pls.’ Ex. C, March 17, 2017, Deposition of Doroth Kammerer-Doak, M.D., (“Depo.”), at 128-29.

A physician is qualified to make a comparison between “the risks he perceives that the [device] poses to patients” and whether the labels “convey these risks to physicians.” *Winebarger*, 2015 WL 1887222, at *15 (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the adequacy of IFUs from a clinical perspective, despite lack of familiarity with FDA regulations and requirements for warnings or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding Dr. Galloway qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings). Indeed, the FDA device regulations say that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known to practitioners* licensed by law to use the device.” 1 C.F.R. § 801.10(c) (emphasis added).

Plaintiffs argue that Dr. Kammerer-Doak’s testimony regarding commonly known risks and the adequacy of the IFU is nevertheless inadmissible as unreliable because she failed to account for studies³ suggesting other not commonly known risk factors (which presumably Plaintiffs will argue should have been included in the IFU). Doc. 6885 at 4-6. For example, Plaintiffs asked her about the so-called 30% shrinkage rate, the association of pain with TVTs, roping and curling, differences between mechanically and laser cut mesh, degradation, and a lack of biocompatibility. Doc. 6882-3, Pls.’ Ex. C, March 17, 2017, Deposition of Doroth Kammerer-Doak, M.D., (“Depo.”), at 115, 159-66. Dr. Kammerer-Doak adequately explained that these risks were already addressed by the IFU or that these risk factors do not occur and, therefore,

³ Furthermore, the “study” she supposedly failed to account for was a professional organization’s mesh complications guideline; she explained that she did not rely on this guideline because it is not cited often in the scientific literature and because it is not specific to TVT slings. Depo. at 121-23.

need not be included in the IFU. *See, e.g., id.* at 115-18 (noting that a lab might have produced 30% shrinkage, but that the scientific literature and her vast clinical experience do not show such shrinkage in the real clinical setting); *id.* at 65-67 (stating that there is no clinical difference between mechanically cut mesh and laser cut mesh, and that no scientific studies have shown any difference in the risks or adverse events from mechanically versus laser cut mesh); *id.* at 159-66 (testifying that there is no scientific evidence that would support a conclusion that TVT slings carry a risk of roping, curling, fraying, degradation, or pore collapse, and that there is no evidence that TVT mesh lacks biocompatibility or causes fibrotic bridging).

Not only is Dr. Kammerer-Doak's testimony regarding risks and the adequacy of the IFU well founded in the scientific literature and her own clinical experience, it is also highly probative as to the question of what risks were properly included in the IFU and those that were properly excluded because they are commonly known or do not exist. As such, it is reliable, based upon solid methodology, and will be quite helpful to the jury. Plaintiffs' motion to exclude this testimony should, therefore, be denied.

II. Dr. Kammerer-Doak's testimony as to pain associated with TVT slings is based upon reliable methodology, including scientific literature and her own evidence-based medical practice.

Plaintiffs challenge Dr. Kammerer-Doak's testimony that TVT is not associated with chronic or longterm pain, arguing that "this type of 'no it's not' *ipse dixit* testimony is not helpful to the jury." Doc. 6885 at 6-7. Dr. Kammerer-Doak opined that "it's possible that [a TVT sling] could cause pain, but it's unlikely; and the association of TVT sling to pain has not been established." Depo. at 87-88 (citing the Schimpf article, which states that the rate of dyspareunia is the same in patients who have had TVT slings, the Burch method, and other types of procedures for stress urinary incontinence). As Plaintiffs note, she based her opinion in part on her own clinical experience using the "TVT sling in more than 1,000 cases and possibly up to

1,500 cases.” *Id.* at 88 (stating that she has never had a patient who has experienced pain attributable to a retropubic sling). She also testified, “I’m also relying on a biological plausibility of a sling that is 1 centimeter . . . wide and very thin and where it’s located within the body. Any surgery . . . has the potential to cause pain, and with the TVT sling, because it’s minimally invasive, and because there’s minimal tissue dissection, the potential for causing pain, as evidenced by the studies and by my personal experience, is minimal.” *Id.* at 88; *see also id.* at 91-92 (explaining the biological plausibility of TVT slings causing chronic pain).

In addition to her own clinical experience with thousands of patients, Dr. Kammerer-Doak also based her opinion on the scientific literature, where “the association of TVT sling to pain has not been established.” Depo. at 87; *see also* Doc. 6882-2 at 21-66 (Dr. Kammerer-Doak’s reliance list, attached to her Report, which is part of Pls.’ Ex. B). At her deposition, she specifically discussed the Schimpf meta-analysis, which compiles numerous studies that reviewed pain. Depo. at 78-84; *see also id.* at 74-78 (citing many studies that had longterm—5 or more years—follow up with respect to safety and adverse events). She testified, “So the information of dyspareunia does come from multiple different studies, yes.” *Id.* at 84.

That no randomized clinical trials, powered specifically to detect chronic pain in TVT patients, have occurred does not undermine the reliability of Dr. Kammerer-Doak’s methodology or testimony.⁴ *See id.* at 103. Her opinions are based upon the available scientific literature, which also comports with her own clinical experience over the past 25+ years. “[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and

⁴ Plaintiffs attempted to undermine Dr. Kammerer-Doak’s reliance on the scientific literature by asking about an article she authored in the late 1990s that noted a mesh erosion rate of 34%. Depo. at 100-02. However, as she explained, that article was written before polypropylene mesh was available; the mesh discussed in that article was made of Gore-Tex, a material that was quickly discontinued for use in urethral sling procedures. *Id.*

specialized experience.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999). Where a physician “has observed minimal complications in [her] clinical practice” and also explains that her “clinical experience . . . is on par with the findings in [the] studies,” that physician’s “clinical experience and review of the scientific literature are sufficiently reliable bases in forming [an] opinion.” *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014).

Dr. Kammerer-Doak’s opinion with respect to the association of TVTs with chronic pain, or the lack thereof, is grounded in her own extensive experience and her review of the available scientific studies. Her opinion is rooted in “sufficiently reliable bases,” and her testimony would be helpful to the jury’s understanding of the scientific evidence and how it plays out in the real-world clinical setting. Plaintiffs’ motion to exclude this opinion testimony should be denied.

III. Dr. Kammerer-Doak has not testified, and will not do so, with respect to her own patient satisfaction or success rates.

Plaintiffs argue that Dr. Kammerer-Doak’s “opinion testimony” related to her own safety or efficacy rates and patient satisfaction should be excluded. Doc. 6885 at 7-8. Dr. Kammerer-Doak has not testified as to her own TVT success rates or patient satisfaction; Plaintiffs have cited no such testimony.

Dr. Kammerer-Doak did testify regarding what the scientific literature has concluded regarding the efficacy or “cure rates” of various surgical treatment options for stress urinary incontinence. *See, e.g.*, Depo. at 92-95, 100-02. She testified that she discusses these rates from the literature with patients when discussing the risks and benefits of the treatment options. *Id.* at 143. She also testified that some patients ask about her personal experience, and she is comfortable giving them her own approximate complication rate even though she does not precisely track such data. *Id.* at 143-44. However, at no point did Dr. Kammerer-Doak actually testify or opine as to what her own approximate complication rates are currently or have been

historically. Moreover, at no point did Dr. Kammerer-Doak even mention patient satisfaction rates.

To the extent Plaintiffs seek to exclude Dr. Kammerer-Doak's testimony as to safety or efficacy rates as reported in the scientific literature, their motion should be denied. Such evidence is relevant and probative, and her testimony will help the jury assess the various risks and benefits involved with TVT and other alternative treatments.

To the extent Plaintiffs seek to exclude the phantom "testimony" as to Dr. Kammerer-Doak's own approximate patient satisfaction or safety/complication rates, their motion is really moot. At any rate, it should be denied. *E.g., compare Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-1617, 2016 WL 2939521, at *33 (S.D.W. Va. May 19, 2016) (allowing broad expert testimony about the safety and efficacy of the device generally, despite the expert's lack of exact statistics from his own clinical experience), *with In re: Ethicon, Inc.*, No. MDL No. 2327, 2016 WL 4542054, at *4 (S.D.W. Va. Aug. 30, 2016) (excluding as unreliable the testimony regarding the "precise statistics" of a physician's own "safety and efficacy rates," which may have included non-Ethicon products and were from an unknown time period and an unknown number of patients).

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion to exclude the general causation testimony of Dr. Dorothy Kammerer-Doak.

Respectfully submitted,

/s/ William M. Gage
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010

Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ Susan M. Robinson
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage